UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,988	12/31/2001	Avigdor Levanon	10793/46	7233

26646 7590 11/14/2007

KENYON & KENYON LLP
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1643	

MAIL DATE	DELIVERY MODE
11/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/029,988	LEVANON ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-57,61-67,72-80 and 98-117 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 1-11, 13-24, 26-57, 61-67, 72-80 and 98-102, 104-115, 116, 117 is/are rejected.

7)☐ Claim(s) 12,25,103 and 115 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 4, 7, 35, 72 and 73 have been amended. Claims 1-57, 61-67, 72-80 and 98-117 are pending and under consideration.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12, 26, 27, 29-32, 34-48, 98-102, 116 and 117 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 7,132,510. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-12 of the '510 patent are drawn in part to peptides or polypeptides dsFv comprising CDR1, CDR2 and CDR3 sequences of SEQ ID NO:114, 115 and

8, respectively, wherein said peptide binds to leukemia cells and cells expressing glycocalin, inlcuding platelets.. The dsFv is a dimer of two scFv linked by a disulfide bond, thus fulfilling the limitations of the instant claims requiring an antibody multimer or antibody dimer.

Claims 1-12, 14-24, 26, 27, 29-32, 34-48, 98-102, 104-114, 116 and 117 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 7,132,510 in view of Gold (U.S. 6,682,886) and Hudson et al (U.S. 5,844,094).

Claims 1-12 of the '510 patent are drawn to peptides or polypeptides comprising Fv molecules including scFv and dsFv comprising CDR1, CDR2 and CDR3 sequences of SEQ ID NO:114, 115 and 8, respectively, wherein said peptide binds to leukemia cells and cells expressing glycocalin, inlcuding platelets. The claims, although drawn to polypeptides and peptides "comprising" a dsFv molecule, do not specifically require a multimer which is more than the dimer of dsFv comprising the CDR1, CDR2 and CDR3 sequences of SEQ ID NO:114, 115 and 8, nor do the claims specifcally require a polypeptide linker whic is Gly4Ser.

Gold teaches that mutivalency can increase the apparent binding affinity of a olecule by orders of magnitude (column 2, lines 64-66).

Hudson et al teach that a preferred linker for ScFv fragments is Gly4Ser which serves to enhance the hydrophilic charertistics of the peptide backbone and provide the linker with enough flexibility (column 8, line 64 to column 9, line 2).

It would have been prima facie obvious at the time the invention was made to link three or four scFv into a trimer or tetramer using a Gly4Ser linker. One of skill in the art would have been motivated to do so by the teachings of Gold on the increase in binding affinity upon multimerization and the teachings of Hudson et al on the preferred use of Gly4Ser as a linker for scFv fragments.

Claims 1-11, 14-24, 26-57, 61-67, 72-80, 98-101, 104-114, 116 and 117 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-20, 23-30, 32, 34-49, 51, 53, 60, 61, 68-72, 75-80, 82-86, 88, 96, 103-107, 110-

115, 117, 118 and 155of copending Application No. 10/032,423 in view of Gold (U.S. 6,682,886) and Hudson et al (U.S. 5,844,094).

Claims 1-11, 14-24, 26-57, 61-67, 72-80, 98-101, 104-114, 116 and 117 are drawn to isolated human antibodies comprising CDR1, CDR2 and CDR3 sequences of SEQ ID NO:114, 115, 8 and 20, and pharmaceutical compositions comprising said antibodies wherein the antibodies are capable of binding to PSGL-1, fibrinogen gamma prime, GP1alpha, heparin, lumican, complement compound 4, interalpha inhibitor, prothrombin, B-cells, AML cells, multiple myeloma cells and metastatic cells, and wherein said antibodies are capable of increasing damage to tumor cells by anti-tumor agnets, inhibt the growth and replication of leukemia cells, inhibt abnormal cell-cell, cell-matrix, platelet-matrix, platelet-platelet or platelet-cell adhesion and inhibit cell rolling

The claims of the '423 application, although drawn to antibodies or complexes of antibodies which comprise SEQ ID NO:114, 115, 8 and 20 do not specifically require a multimer comprising the CDR1, CDR2 and CDR3 sequences of SEQ ID NO:114, 115 and 8, nor do the claims specifcally require a polypeptide linker whic is Gly4Ser.

Gold teaches that mutivalency can increase the apparent binding affinity of a olecule by orders of magnitude (column 2, lines 64-66).

Hudson et al teach that a preferred linker for ScFv fragments is Gly4Ser which serves to enhance the hydrophilic charertistics of the peptide backbone and provide the linker with enough flexibility (column 8, line 64 to column 9, line 2).

It would have been prima facie obvious at the time the invention was made to l link the antibodies of the '423 application into a dimer, trimer or tetramer trimer or tetramer using a Gly4Ser linker. One of skill in the art would have been motivated to do so by the teachings of Gold on the increase in binding affinity upon multimerization and the teachings of Hudson et al on the preferred use of Gly4Ser as a linker for scFv fragments.

This is a provisional obviousness-type double patenting rejection.

Claims 1-11, 14-24, 26, 27, 30, 31, 32, 34-57, 61-67, 72-80, 98-101, 104-114, 116 and 117 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18, 20, 23, 26-51, 57-72, 76-78, 80-86, 91-107, 111-113, 115,

116, 156, 165, 166, 170 and 171 of copending Application No. 10/189,258 in view of Gold (U.S. 6,682,886) and Hudson et al (U.S. 5,844,094).

The claims of the '258 application, although drawn to antibodies or complexes of antibodies which comprise SEQ ID NO: 8 and phamraceutical compositions comprising said antibodies wherein the antibodies are capable of binding to PSGL-1, fibrinogen gamma prime, GP1alpha, heparin, lumican, complement compound 4, interalpha inhibitor, prothrombin, B-cells, AML cells, multiple myeloma cells and metastatic cells, and wherein said antibodies are capable of increasing damage to tumor cells by anti-tumor agnets, inhibt the growth and replication of leukemia cells, inhibt abnormal cell-cell, cell-matrix, platelet-matrix, platelet-platelet or platelet-cell adhesion and inhibit cell rolling do not specifically require a multimer comprising the SEQ ID NO: 8, nor do the claims specifcally require a polypeptide linker whic is Gly4Ser.

Gold teaches that mutivalency can increase the apparent binding affinity of a olecule by orders of magnitude (column 2, lines 64-66).

Hudson et al teach that a preferred linker for ScFv fragments is Gly4Ser which serves to enhance the hydrophilic charertistics of the peptide backbone and provide the linker with enough flexibility (column 8, line 64 to column 9, line 2).

It would have been prima facie obvious at the time the invention was made to link the antibodies of the '258 application into a dimer, trimer or tetramer using a Gly4Ser linker. One of skill in the art would have been motivated to do so by the teachings of Gold on the increase in binding affinity upon multimerization and the teachings of Hudson et al on the preferred use of Gly4Ser as a linker for scFv fragments.

This is a provisional obviousness-type double patenting rejection.

Claims 12, 25, 103 and 115 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

All other rejections and objections as set forth or maintained in the previous Office action are withdrawn in light of applicants amendments and arguments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A. Canella/
Ph.D., Primary Examiner
Art Unit 1643